



APR - 8 1998

UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
ASSISTANT SECRETARY AND COMMISSIONER  
OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

#23

Todd M. Crissey  
Patent Department  
WARNER-LAMBERT COMPANY  
2800 Plymouth Road  
Ann Arbor, MI 48105

Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,260,769

Dear Mr. Crissey:

An order granting an interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,260,769 for a period of one-year. An appropriate notice thereof will be published in the Official Gazette.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson  
Karin Tyson  
Senior Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 15-22  
Rockville, MD 20857

RE: CEREBYX® (fosphenytoin sodium)  
FDA Docket No.: 96E-0442

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE COMMISSIONER OF PATENTS AND TRADEMARKS

In re  
Request for Patent Term Extension  
U.S. Patent No. 4,260,769

:  
ORDER GRANTING  
INTERIM EXTENSION

Warner-Lambert Company, agent of Merck & Co., Inc., the owner of record in the Patent and Trademark Office (PTO) of U.S. Patent No. 4,260,769, filed an application for patent term extension under 35 U.S.C. § 156 on August 30, 1996. The original term of the patent is due to expire on April 7, 1998. The patent claims the active ingredient fosphenytoin sodium in the human drug product "CEREBYX®" which was approved by the Food and Drug Administration for commercial marketing or use on August 5, 1996. An extension of 1,826 days is requested.

The initial PTO review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. However, in accordance with the limitation of 35 U.S.C. § 156(g)(6)(B), applicant appears entitled to an extension of five years. Since the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,260,769 is granted for a period of one year from the original expiration date of the patent.

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Date



Bruce A. Lehman  
Assistant Secretary of Commerce and  
Commissioner of Patents and Trademarks